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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,167	09/20/2001	Jeffrey L Wrana	3477-91	3921
20792	7590	02/13/2004	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			KIM, YOUNG J	
			ART UNIT	PAPER NUMBER
			1637	
DATE MAILED: 02/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/744,167

Applicant(s)

WRANA, JEFFREY L

Examiner

Young J. Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-44 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Preliminary Remark

The preliminary amendment received on January 19, 2001 to claims 13, 14, 16, and 43 is acknowledged.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The special technical feature which links the inventions is determined to be SARA protein. Tsukazaki et al. (Cell, 1998, vol. 95, pages 779-791) disclose SARA, a FYVE Domain protein that recruits Smad2 to the TGF β receptor. Therefore, the special technical feature of the instant application lacks novelty, and the instant restriction is applied. Applicants are reminded that a restriction practice with regard to a National Stage application is governed under the unity of invention and not search burden.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 4, 6, 7, 8, 11-14, and 16-18, drawn to a polynucleotide encoding a mammalian SARA protein, a vector comprising the polynucleotide, a host cell comprising the vector, and a method of using the polynucleotide to produce the encoded polypeptide.

Group II, claim(s) 1, 3, 5, 6, 9-14, and 16-18, drawn to a polynucleotide encoding a non-mammalian SARA protein, a vector comprising the polynucleotide, a host cell

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comprising the vector, and a method of using the polynucleotide to produce the encoded polypeptide.

Group III, claim(s) 15, drawn to an isolated polynucleotide encoding a SARA protein FYVE domain.

Group IV, claim(s) 19, 20, 22, 23, 25-29, and 31-34, drawn to a substantially pure mammalian SARA protein and its homolog.

Group V, claim(s) 19, 21, 24, 28, 29, 31, and 32, drawn to a substantially pure non-mammalian SARA protein.

Group VI, claim(s) 30, drawn to a substantially pure polypeptide.

Group VII, claim(s) 35 and 36, drawn to a substantially pure antibody and a cell line producing the antibody.

Group VIII, claim(s) 37, drawn to a method for identifying an allelic variant of homolog of a human SARA gene.

Group IX, claim(s) 38, 39, and 41, drawn to a method for modulating binding of SARA protein.

Group X, claim(s) 40, drawn to a method of preventing or treating a disorder associated with SARA protein.

Group XI, claim(s) 42 and 43, drawn to a non-human transgenic animal comprising a polynucleotide encoding a heterologous SARA protein.

Group XII, claim(s) 44, drawn to a non-human knockout animal lacking a SARA gene.

The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special

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technical features for the following reasons: As discussed above, the special technical feature providing for the unity of invention, determined as being SARA protein, lacks novelty as evidenced by Tsukazaki et al. (Cell, 1998, vol. 95, pages 779-791), attached hereto. Therefore, the inventions are restricted as set forth above. Additionally, Applicants are advised that claims 6, 11, and 32 recites a polynucleotide sequences encoding SARA protein from both human and non-mammalian subjects. As reflected by Groups I and II, these are different inventions, evidenced by their different sequences. Therefore, Applicants are advised that claims 6, 11, and 32 will be examined to the extent of the elected invention. For example, if a polynucleotide encoding for a non-mammalian SARA protein is elected, then the polynucleotide sequences encoding for mammalian SARA protein will not be included in the examination and the claim will be objected to for being drawn to non-elected invention.

A telephone call was not made to request an oral election to the above restriction requirement due to the complex nature of the requirement (MPEP § 812.01).

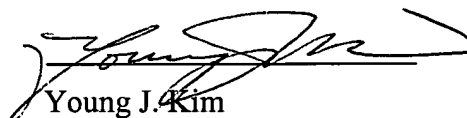
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be

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reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (517) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0507.



Young J. Kim
Patent Examiner
Art Unit 1637
1/30/04